# Exhibit G

# AFFIDAVIT OF BRUCE ROSENZWEIG, M.D.

STATE OF ILLINOIS )
) ss
COUNTY OF COOK )

1. I, Bruce Rosenzweig, M.D., am over the age of 18 and fully competent to testify to the matters stated herein.

2. I have personal knowledge of the facts stated herein.

3. My knowledge of Randomized Controlled Trials ("RCTs") is informed not only by having reviewed large numbers of them, but also be personal participation in them.

4. I was involved in the development of a new medical device, an Amnio-infusion catheter. As part of that process, I helped to design an RCT to test placing the catheter into the uterus versus placing a single sham catheter. Once we started inventing the double lumen catheter, we considered different embodiments to determine which was most effective.

5. I worked with EMPI on developing and testing the Innova electrical simulator to treat SUI, and helped to design an RCT to test it. The RCT tested using a sham versus using an active simulator placed in the vagina. I was on the scientific advisory board of the company, so I was not an investigator, but I did help to design the RCT.

6. I was an investigator for an RCT involving the Lea Shield and Fem cap, which were both cervical cap contraceptives. They required a prescription, and the trial was designed to determine the appropriate size to achieve efficacy and to gain clearance from the FDA to sell the devices over the counter.

7. As I have discussed on many occasions, long-term clinical trials provide more reliable information about safety and efficacy than do short-term trials. However, the value of shorter-term trials is greater in evaluating efficacy than in evaluating safety.

8. For instance, the three-year Okulu study showing that using Ultrapro mesh to cure SUI is effective is valuable information because if the sling were ineffective, it would not cure SUI for that period of time. However, mesh complications often do not manifest for several years, so the length of a study is particularly important with regard to safety.

FURTHER, affiant sayeth naught.

In witness whereof, I have affixed my signature this 9th day of May, 2016.

Bruce Rosenzweig, M.D.

Subscribed and sworn to before me, this 9th day of May, 2016.

NOTARY PUBLIC

My Commission Expires:

8/25/17

OFFICIAL SEAL
KATIE ENGEL
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:08/25/17

Gynecare

# TVT™

Tension-free Support
for Incontinence

**GYNECARE TVT™**
**Tension-free Vaginal Tape**

**GYNECARE TVT™ Single Use Device**
**GYNECARE TVT™ Reusable Introducer**
**GYNECARE TVT™ Reusable Rigid Catheter Guide**

**GYNECARE TVT™ anordning til engangsbrug**
**GYNECARE TVT™ indfører til flergangsbrug**
**GYNECARE TVT™ stift guiding kateter til flergangsbrug**

**GYNECARE TVT™ hulpmiddel voor eenmalig gebruik**
**GYNECARE TVT™ herbruikbare introducer**
**GYNECARE TVT™ herbruikbare starre kathetervoerder**

**GYNECARE TVT™ -laite, kertakäyttöinen**
**GYNECARE TVT™ -sisäänviejä, kestokäyttöinen**
**GYNECARE TVT™ -katetrinohjain, kestokäyttöinen, jäykkä**

**Dispositif GYNECARE TVT™ à usage unique**
**Introducteur réutilisable GYNECARE TVT™**
**Guide de sonde rigide réutilisable GYNECARE TVT™**

**GYNECARE TVT™ Einmal-Implantat**
**GYNECARE TVT™ wiederverwendbares Einführungsinstrument**
**GYNECARE TVT™ wiederverwendbare starre Katheterführung**

**Συσκευή μιας χρήσης GYNECARE TVT™**
**Επαναχρησιμοποιήσιμος εισαγωγέας GYNECARE TVT™**
**Επαναχρησιμοποιήσιμος άκαμπτος οδηγός καθετήρα GYNECARE TVT™**

**Dispositivo monouso GYNECARE TVT™**
**Introduttore riutilizzabile GYNECARE TVT™**
**Guida rigida riutilizzabile per catetere GYNECARE TVT™**

**Dispositivo de utilização única GYNECARE TVT™**
**Introdutor reutilizável GYNECARE TVT™**
**Guia rígido de cateter reutilizável GYNECARE TVT™**

**Sistema para un solo uso GYNECARE TVT™**
**Introductor reutilizable GYNECARE TVT™**
**Guía de catéter rígida reutilizable GYNECARE TVT™**

**GYNECARE TVT™ produkt för engångsbruk**
**GYNECARE TVT™ återanvändbar införare**
**GYNECARE TVT™ återanvändbar stel kateterguide**

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Made in Switzerland


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**GYNECARE TVT™ Single Use Device**
**GYNECARE TVT™ Reusable Introducer**
**GYNECARE TVT™ Reusable Rigid Catheter Guide**

**Please read all information carefully.**
Failure to properly follow instructions may result in improper functioning of the device and lead to injury.

**Important:**
This package insert is designed to provide instructions for use of the Tension-free Vaginal Tape single use device, Reusable Introducer, and Reusable Rigid Catheter Guide. It is not a comprehensive reference to surgical technique for correcting Stress Urinary Incontinence (SUI). The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the GYNECARE TVT™ Device. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

**DESCRIPTION (System)**
GYNECARE TVT consists of the following:

GYNECARE TVT™ Single Use Device, provided sterile (available separately)
GYNECARE TVT™ Reusable Introducer, provided non-sterile (available separately)
GYNECARE TVT™ Reusable Rigid Catheter Guide, provided non-sterile (available separately)

**GYNECARE TVT DEVICE**
The GYNECARE TVT Device is a sterile single use device, consisting of one piece of undyed or blue (Phthalocyanine blue, color index. Number 74160) PROLENE™ Polypropylene Mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.
The GYNECARE TVT Device is available in either mechanical cut or laser cut versions for the physician's preference. To determine if the GYNECARE TVT Device implant is mechanical or laser cut, consult the product code on the device packaging; an (L) at the end of the number indicates the laser cut mesh.
PROLENE Mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE™ polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7 mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE Mesh is knitted by a process which interlinks each fiber junction.

**GYNECARE TVT INTRODUCER**
The GYNECARE TVT Introducer is provided non-sterile and is reusable. The Introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The Introducer is intended to facilitate the passage of the GYNECARE TVT Device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

**GYNECARE TVT RIGID CATHETER GUIDE**
The GYNECARE TVT Rigid Catheter Guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

**INDICATIONS**
The GYNECARE TVT Device is intended to be used as a pubourethral sling for treatment of Stress Urinary Incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT Introducer and Rigid Catheter Guide are available separately and are intended to facilitate the placement of the GYNECARE TVT Device.

**PATIENT FACTORS**
Physicians should use their surgical experience and judgment to determine if PROLENE Mesh is appropriate for certain patients. Patient-specific factors may impair wound healing, which may increase the likelihood of adverse reactions.

**INSTRUCTIONS FOR USE**

1. The procedure can be carried out under local anesthesia only. It can also be performed using regional or general anesthesia.
2. Before the patient is prepped and draped, she should be placed in the lithotomy position taking care to avoid hip flexion greater than 60°.
3. Insert an 18 French Foley catheter and leave it to open drainage.
4. At the level of the mid urethra, inject a small amount of local anesthesia submucosally to create a space between the vaginal wall and the periurethral fascia. The extent of dissection required for placement is minimal. Only a small paraurethral incision is required over the mid urethra to position the tip of the Needle. Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.5 cm long starting approximately 1.0 cm cephalad from the urethral meatus. This incision will be positioned over the mid-urethral zone and will allow for subsequent passage of the Implant.
5. With a small pair of blunt scissors, make two small paraurethral lateral dissections (approximately 0.5 to 1.0 cm) to accommodate the tips of the Needle.
6. Identify the two Needle exit sites, which should be 2-2.5 cm on each side of the midline, immediately above the pubic symphysis. Either mark these sites or, if desired, place two small 3-4 mm transverse stab incisions at the intended exit site. In order to avoid the inferior epigastric vessels it is important that the intended exit sites be not more than 2.5 cm from the midline. It is important that the exit sites for the Needle passages be near the midline and close to the superior aspect of the pubic bone, in order to avoid anatomic structures in the abdomen, inguinal area and lateral pelvic sidewall.
7. If retropubic infiltration of local anesthesia is not performed then consider infiltrating the retropubic space with two injections of normal saline on either side of midline. Starting at the needle exit sites pass an 18 gauge needle along the back of the pubic bone until the tip of the needle touches the endopelvic fascia. As the needle is withdrawn inject 30 to 50 cc. By so doing it opens up the retropubic space to minimize the risk of bladder puncture during retropubic Needle passage.
8. Confirm that all urine has been drained from the bladder. Once the bladder is empty, insert the GYNECARE TVT Reusable Rigid Catheter Guide (available separately) into the channel of the 18 French Foley catheter. The handle of the GYNECARE TVT Reusable Rigid Catheter Guide should be fixed around the catheter at its proximal end. The purpose of placing the GYNECARE TVT Reusable Rigid Catheter Guide into the catheter is to allow contralateral displacement of the bladder, bladder neck and urethra away from the tip of the Needle as it passes through the retropubic space.
9. The threaded end of the Introducer is screwed into the end of one of the needles.
10. Gently push the tip of the 18 French Foley catheter toward the posterior lateral wall of the bladder opposite to the intended Needle passage. For example, by pushing toward the patient's left side the bladder will go from a spherical to a spheroid configuration. This moves the bladder away from the back of the pubic symphysis. Additionally, it moves the bladder neck and the urethra to the left as the Needle is passed on the patient's right side, thereby minimizing the risk of bladder perforation.
11. Hold the Introducer Handle using your dominant hand. Pass the tip of the Needle that is mounted on the GYNECARE TVT Introducer, paraurethrally through the urogenital diaphragm at the level of the midurethra. Initial insertion of the device is controlled by using the tip of the index finger of the non-dominant hand, which is placed in the vagina under the anterior vaginal wall, just lateral to the suburethral incision. The curved part of the Needle should rest in the palm of the non-dominant hand. Pass the Needle through the urogenital diaphragm into the retropubic space. During the initial placement into the paraurethral dissected space the Needle tip should be oriented horizontally, i.e. in the frontal plane. During passage through the urogenital diaphragm lower the Introducer handle to ensure that the Needle tip passes vertically while staying in close contact to the back of the pubic symphysis. After passage through the urogenital diaphragm resistance to the passage of the Needle is significantly reduced once it enters the retropubic space.

12. At this point, the non-dominant hand is moved from the vagina to the supra-pubic exit site. The Needle tip is guided through the retropubic space staying as close to the back of the pubic symphysis as possible. This is achieved by lowering the GYNECARE TVT Introducer Handle, thereby pressing the Needle tip against the back of the pubic bone.
13. During passage through the retropubic space aim the Needle tip towards the pre-marked abdominal exit site.
14. When the needle tip has reached the abdominal incision unscrew the GYNECARE TVT Introducer from the Needle. Before the Implant is pulled into place, remove the 18 French Foley catheter and perform a cystoscopy (70 degree lens recommended).
15. Once bladder integrity is confirmed, pull the Needle upward to bring the Implant out through the abdominal exit site. Clamp the Implant just below the Needle. Cut the Implant between the connection to the Needle and the clamp.
16. The procedure is now repeated on the patient's other side while repeating steps 9 – 15. NOTE: IN ORDER TO MINIMIZE THE RISK OF BLADDER INJURY, IT IS IMPORTANT THAT THE BLADDER BE DISPLACED TO THE CONTRALATERAL SIDE USING THE MANEUVERS OUTLINED IN STEP 10.
17. The ends of the implant are then pulled upward to bring the implant (sling) loosely, i.e., without tension, under the midurethra. Adjust the Implant so that leakage is reduced, allowing only a few drops of urinary leakage to occur under stress. For this, use patient feedback, i.e. coughing with a full bladder (approximately 300 mL).
18. Grasp the Implant Sheaths that surround the Implant with clamps, taking care not to grasp the Implant. Then individually remove the Implant Sheaths by gently pulling up on the clamps, away from the abdomen, one at a time. To avoid putting tension on the Implant, a blunt instrument (scissors or forceps) should be placed between the urethra and the Implant during removal of the Implant Sheaths.
19. **NOTE: Premature removal of the sheath may make subsequent adjustments difficult.**
20. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture the implant.
21. Close the skin incisions with suture or surgical skin adhesive.
22. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

**CONTRAINDICATIONS**

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE Mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

**WARNINGS AND PRECAUTIONS**

- Do not use GYNECARE TVT in patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT in a patient who has a urinary tract infection.
- Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in the GYNECARE TVT implantation procedure before employing the GYNECARE TVT Device. It is important that the tape be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimize risks.
- Retropubic bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from the hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The Rigid Catheter Guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley catheter.
- When removing the Rigid Catheter Guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.

- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE Mesh if contaminated, place should be dealt with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical experience is available with vaginal delivery following the procedure, in case of pregnancy delivery via cesarean section is recommended.
- Post-operatively, the patient is recommended to refrain from heavy lifting and/or exercise (i.e., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following the procedure. To minimize this risk, make sure to place the tape tension-free in the mid-urethral position.
- Do not contact the PROLENE Mesh with any staples, clips or clamps, as mechanical damage to the mesh may occur.
- Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.
- Discard opened, unused devices.

**ADVERSE REACTIONS**

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

**OTHER ADVERSE REACTIONS**

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death

**ACTIONS**

Animal studies show that implantation of PROLENE Mesh elicits a minimal inflammatory reaction in tissues and stimulates the deposition of a thin fibrous layer of tissue that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

**INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS (GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide)**

To ensure the reliability and functionality of the GYNECARE TVT Introducer and GYNECARE TVT Rigid Catheter Guide, clean the instruments before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instruments. Prior to cleaning, the GYNECARE TVT Introducer should be separated into its component parts (handle and threaded shaft). The Introducer is reassembled after cleaning and before sterilization.

**Manual Method:**

1. Soak the instrument components in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86°F to 95°F (30°C to 35°C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument components in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument components may be treated with instrument lubricant.

**Automated Method:**

Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below:

- Rinse/Wet Cycle Cold Water – 1 minute
- Wash 176°F (80°C) – 12 minutes
- Rinse Cycle – 1 minute
- Rinse Cycle – 12 minutes
- Final Rinse – 2 minutes
- Rinse with Demineralized water 176°F (80°C) – 2 minutes
- Dry 199.4°F (93°C) – 10 minutes

**STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS (GYNECARE TVT Introducer, GYNECARE TVT Rigid Catheter Guide)**

The GYNECARE TVT Introducer and GYNECARE TVT Rigid Catheter Guide are supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270°F to 284°F (132°C to 140°C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

**INSTRUMENT MAINTENANCE**

- GYNECARE TVT Introducer

Before each use, inspect the threaded parts of the inner shaft.

- GYNECARE TVT Rigid Catheter Guide

Before each use, inspect the instrument. Check to ensure that the long end which traverses the catheter channel has no sharp edges or burrs.

**HOW SUPPLIED**

The GYNECARE TVT Device is provided sterile (ethylene oxide) for single use. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened, unused devices. The reusable GYNECARE TVT Introducer and GYNECARE TVT Rigid Catheter Guide are supplied separately and are non-sterile. These accessories are to be cleaned and sterilized prior to each use as described above.

**STORAGE**

No special storage conditions required. Do not use after expiration date.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

**Symbols Used on Labeling**

| | |
|---|---|
|  | Do not reuse |
|  | Do not resterilize |
|  | Use by date |
| REF | Catalogue number |
|  | Caution |
|  | Manufacturer |
| CE 0086 | CE mark and identification number of Notified Body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC |
| Rx only | Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner. |
|  | Do not use if package is damaged |
| STERILE EO | Sterilized using Ethylene Oxide |
| LOT | Batch code |